Summary of Performance Standards

21 CFR 1020.10. **Television Receivers**

- applies to receivers and monitors that receive and convert a signal to display a "television picture"
- limits radiation at 5 cm from the surface to 0.5 mR/hr during conditions of maximized user and service controls and a single worst-case component fault

21 CFR 1020.20. **Cold-cathode Discharge Tubes**

- limits radiation at 30 cm to 10 mR/hr
- requires user precautions labeling

21 CFR 1020.30. **Diagnostic X-Ray Systems and their Major Components**

- applies to tube housings, generators and controls, film changers; fluoroscopic assemblies; spot film and image intensifiers; cephalometric devices; image receptor support devices for mammographic systems; diagnostic systems; CT systems (in part)
- limits leakage at 1 meter from the source to 100 mR in 1 hr and at 5 cm from any other components to 2 mR in 1 hr
- specifies beam limitations and beam quality criteria; user and assembler instructions and technical information

21 CFR 1020.31. **Radiographic Equipment**

- requires control and indication of technique factors; timer termination conditions; accuracy and reproducibility specifications; indication and limits on field size and alignment, etc.
- limits transmission through mammographic image support system at 5 cm to 0.1 mR for each tube activation

21 CFR 1020.32. **Fluoroscopic Equipment**

- requires primary protective barrier; field limitation; continuous pressure control; source to skin distance; timer
- limits entrance exposure rates to 5 R/min (or 10 R/min with automatic exposure rate control)

CFR 1020.33. **Computed Tomography (CT) Equipment**

- specifies user information on dose, imaging performance and quality assurance
- requires indication prior to initiation of scan, timer control to terminate or shutter the beam, indication of plane and alignment; beam on and shutter status indicators

21 CFR 1020.40. **Cabinet X-Ray Systems**

- applies to systems with x-ray tube installed in an enclosure, including carry-on baggage inspection systems
- limits radiation at 5 cm to 0.5 mR/hr under maximized operating conditions and door positions; restricts human access to the primary beam
- requires 2 interlocks on each door with 1 resulting in physical disconnection of energy to the generator; key control; 2 independent x-ray on indicators; warning indicators and labels; user instructions, etc.

21 CFR 1030.10. **Microwave Ovens**

- applies to ovens for heating and cooking food (household or commercial)
- limits radiation at 5 cm to 1 mW per sq cm prior to purchase and 5 mW per sq cm throughout useful life under conditions of allowable door positions and primary interlock failure, or with conducting wire
- limits access by human body to energy-containing space and to 1 of 2 required interlocks; at least 1 interlock must be "monitored" to disable the source
- requires user caution label and user and service manuals

21 CFR 1040.10. **Lasers and Laser Systems**

- applies to lasers, products containing lasers, and products intended to contain lasers
- specifies classification and user logotype with precautions based on radiation accessible during use; limits radiation from viewing optics, ports and displays to less than Class I; specifies interlocks/labels based on radiation accessible during maintenance and service

- requires, based on increasing hazard class, radiation indicators and safety: aperture label, beam attenuator, emission indicator (some with time delay), remote door interlock, key control, scanning safeguards, etc.

- requires user, maintenance and service manuals

21 CFR 1040.11. **Specific Laser Products**

- requires indication of power levels on medical lasers with +/- 20% accuracy

- limits radiation to less than Class IIIa for surveying, leveling and alignment lasers

- limits radiation to less than Class IIIa for demonstration lasers, including display or entertainment (NOTE: Variances, with extensive human access limitations, are often granted for laser light shows.)

21 CFR 1040.20. **Sunlamps and Sunlamp Products**

- applies to products intended to produce skin tanning

- limits levels of UV-C radiation and ratio of UV-A/ UV-B; requires specification of compatible lamps

- requires maximum exposure time based on ultraviolet levels, timers with +/- 10% accuracy, protective eyewear, and user labeling and instructions

21 CFR 1040.30. **High-intensity Mercury Vapor Discharge Lamps**

- requires self-extinguishing lamps to cease operating after breakage or removal of 3 sq. cm of the outer envelope

- specifies lamp packaging and advertisement information

21 CFR 1050.10. **Ultrasonic Therapy Products**

- applies to applicators or generators operating above 16 kHz for physical therapy

- provides indication of radiation parameters: average and temporal peak power and/or intensity; pulse duration, pulse repetition rate; effective radiating area; beam nonuniformity and spatial distributions, etc.

- requires power accuracy of +/- 20% and timer accuracy +/- 10%

Summary of Reporting Requirements

21 CFR 1010.4, 1010.5. **Variances; Exemptions**

- manufacturers may request variances (i.e., an individual standard) for alternate, or equivalent, safety
- manufacturers may request exemption from a performance standard for reason of national security, investigations, etc.

21 CFR 1002.20. **Accidental Radiation Occurrences**

- required for ALL electronic products immediately after the event
- documents any actual or possible unexpected exposure during manufacturing, testing or use of the product

21 CFR 1002.10-12. **Product Reports (also Supplements, Abbreviated)**

- applies to products listed in Table 1 of 1002.1 (most are subject to performance standards)
- documents information on manner of conformity to standards, labeling, test instrumentation, test procedures, quality control, etc.; submitted prior to family of products being introduced into commerce
- abbreviated reports were added in Oct 1995 to reduce burdens

21 CFR 1002.13. **Annual Reports**

- applies to products as listed in Table 1
- documents results of testing and user safety concerns; annually or quarterly updates contain model listings

Table 1.--Record and Reporting Requirements by Product

Products	Manufacturer						Dealer/ Distributor
	Product reports §1002.10	Supplemental reports §1002.11	Abbreviated reports §1002.12	Annual reports §1002.13	Test records §1002.30(a) [1]	Distribution records §1002.30(b) [2]	Distribution records §1002.40,.41
DIAGNOSTIC X RAY [3] (§§1020.30—1020.33)							
Computed Tomography	X	X		X	X	X	X
X-ray System [4]	X	X		X	X	X	X
Tube Housing Assembly	X	X		X	X	X	
X-ray Control	X	X		X	X	X	X
X-ray High Voltage Generator	X	X		X	X	X	X
X-ray Table or Cradle			X		X	X	X
X-ray Film Changer			X		X	X	
Vertical Cassette Holders Mounted in a Fixed Location and Cassette Holders with Front Panels			X		X	X	X
Beam-limiting Devices	X	X		X	X	X	X
Spot-film Devices and Image Intensifiers Manufactured After April 26, 1977	X	X		X	X	X	X
Cephalometric Devices Manufactured After February 25, 1978			X		X	X	
Image Receptor Support Devices for Mammographic X-ray Systems Manufactured After September 5, 1978			X		X	X	X
CABINET X RAY (§1020.40)							
Baggage Inspection	X	X		X	X	X	X
Other	X	X		X	X	X	
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET X RAY							
Medical			X	X	X	X	
Analytical			X	X	X	X	
Industrial			X	X	X	X	
TELEVISION PRODUCTS (§1020.10)							
<25 kilovolts (kV) and <0.1 milliroentgen per hr (mR/hr) IRLC [5] [6]			X	X [6]			
25 kV and <0.1 mR/hr IRLC [5]	X	X		X			
0.1 mR/hr IRLC [5]	X	X		X	X	X	
MICROWAVE/RF							
MW Ovens (§1030.10)	X	X		X	X	X	
MW Diathermy			X				
MW Heating, Drying, Security Systems			X				
RF Sealers, Electromagnetic Induction Heating Equipment, Dielectric Heaters (2-500 megahertz)			X				
OPTICAL							
Phototherapy Products	X	X					
Laser Products (§§1040.10,1040.11)							
Class I Lasers and Products Containing such Lasers [7]	X			X	X		
Class I Laser Products Containing Class IIa,II,IIIa Lasers [7]	X			X	X	X	
Class IIa,II,IIIa Lasers and Products other than Class I Products Containing such Lasers [7]	X	X		X	X	X	X
Class IIIb & IV Lasers and Products Containing such Lasers [7]	X	X		X	X	X	X
Sunlamp Products (§1040.20)							
Lamps Only	X						
Sunlamp Products	X	X		X	X	X	X
Mercury Vapor Lamps (§1040.30)							
T Lamps	X	X		X			
R Lamps			X				
ACOUSTIC							
Ultrasonic Therapy (§1050.10)	X	X		X	X	X	X
Diagnostic Ultrasound			X				
Medical Ultrasound other than Therapy or Diagnostic	X	X					
Non-medical Ultrasound			X				

[1] However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.

[2] The requirement includes §§1002.31 and 1002.42, if applicable.

[3] Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see §21 CFR 1020.30(d)(1) through (d)(3).

tems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in §21 CFR 1020.30(c).

termined using the Isoexposure Rate Limit Curve (IRLC) under Phase III test conditions (§1020.10(c)(3)(iii)).

[6] Annual Report is for production status information only.

[7] Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.